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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/766,511	01/19/2001	Scan A. McCarthy	10147-65	9759
			(MPI2000-537OMNI)	
			EXAMINER	
			JIANG, DONG	
			ART UNIT	PAPER NUMBER
			1646	
DATE MAILED: 06/14/2004				

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BOSTON, MA 02110-2804

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/766,511

Applicant(s)

MCCARTHY ET AL.

Examiner

Dong Jiang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-7, 12, 31 and 44-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12, 31 and 44-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED OFFICE ACTION**

The request filed on 25 March 2004 for a Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/766,511 is acceptable, and a RCE has been established. An action on the RCE follows.

Applicant's amendment filed on 25 March 2004 is acknowledged and entered. Following the amendment, claims 8-11, 13-30 and 32-43 are canceled, and claims 1, 2, 4, 31 and 44 are amended.

Currently, 1-7, 12, 31 and 44-46 are pending, and under consideration.

#### **Withdrawal of Objections and Rejections:**

The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in view of applicant's amendment.

#### **Objections and Rejections under 35 U.S.C. §101 and §112:**

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-7, 12, 31 and 44-46 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by a credible, substantial, specific, or well-established utility, for the reasons of record set forth in the previous Office Actions, paper No. 17, mailed on 23 April 2003, and on 04 November 2003.

Applicants argument filed on 25 March 2004 has been fully considered, but is not deemed persuasive for reasons below.

At pages 6-8 of the response, the applicant argues that the information provided in the present application regarding TANGO405 is very similar to that provided in Example 10 of the USPTO Training Material for the Revised Interim Utility Guidelines, in which it was found that a "well established utility" was given. Further, applicants provide a chart to compare the

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information provided in Example 10 of the Training Material and in the instant application, such as that both murine dectin-2 and the present human TANGO405 include a C-type lectin domain, and argue that applicants have provided more information than needed to demonstrate a credible, substantial, specific or well established utility according to Example 10 of the Training Material, and that human TANGO405 is a human ortholog of dectin-2 having similar biological activity. Applicants further argue, at page 8 of the response, that the high level of sequence identity in a conserved relevant domain of dectin-2 provides further evidence that murine dectin-2 and human TANGO405 have similar biological function. This argument is not persuasive for the following reasons:

With respect to Example 10 of the Training Material, it is directed to a novel amino acid sequence of SEQ ID NO:3 encoded by a polynucleotide of SEQ ID NO:2, and the polypeptide has a similarity score of 95% to known amino acid sequences of DNA ligases, and therefore SEQ ID NO:3 is a DNA ligase, indicating specific, substantial and credible utility. The instant situation is completely different from that of DNA ligases because in the enzyme art, the functional activity is predictable when a polypeptide shares a high homology, such as 95%, to known enzymes, which, in general, have decisive and specific enzymatic activity, and the main function of DNA ligases is to ligate DNA regardless of different molecules of DNA ligases. In contrast, members of C-type lectin are extremely diverse with respect to their functional properties (discussed in more detail below). As such, the situation of DNA ligase in Example 10 of the Training Material is not suitable in the instant case.

Further, with respect to the argument that both murine dectin-2 and the present human TANGO405 include a C-type lectin domain, and that human TANGO405 is a lectin ortholog of dectin-2, the main issue is not whether the present TANGO405 is a member of C-type lectin family, rather, the issue is that, even if TANGO405 may be a C-type lectin, the function of C-type lectins is known in the art to be diverse and *not predictable* merely based upon the sequence homology. For example, Arizumi et al. (US6,046,158) teaches that C-type lectins are a family of glycoproteins that exhibit amino acid sequence similarities in their carbohydrate recognition domains (CRD), and have been subdivided into four categories (column 1, lines 58-62), that C-type lectins are known to function as agglutinins, opsonins, complement activators,

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and cell-associated recognition molecules, and thus C-type lectins exhibit diverse functions with biological significance (column 2, the second paragraph). As such, even though all C-type lectins share some common sequence structures, it does not mean that they share similar functional properties. The present application does not disclose any functional property or biological significance that is *directly associated with the human TANGO405*, and mere indication that the TANGO405 is a member of C-type lectin family or a lectin ortholog of dectin-2 is not sufficient to establish a substantial, specific, or well-established utility for the claimed molecule for the reasons addressed above. Therefore, the rejection of the claims under 35 U.S.C. 101 is maintained.

*Note:* the newly cited reference is merely used to rebut applicants argument, and it is not for sustaining any new ground of rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-7, 12, 31 and 44-46 remain rejected under 35 U.S.C. 112, first paragraph, for the reasons of record set forth in the previous Office Actions, paper No. 17, mailed on 23 April 2003, and on 04 November 2003.

Applicants argument filed on 25 March 2004 has been fully considered, but is not deemed persuasive for the reasons above.

Furthermore, *even if* the specification taught how to use human TANGO405, enablement would remain not being commensurate in scope with claim 1, and the dependent claims 3-7, 12, 45 and 46, for the reasons of record set forth in the previous Office Actions, paper No. 17, mailed on 23 April 2003, and on 04 November 2003.

Applicants argument filed on 25 March 2004 has been fully considered, but is not deemed persuasive for reasons below.

At page 9 of the response, the applicant argues 1) that the claims recite that nucleic acid molecules include at least 40 nucleic acids or encode a fragment of 15 amino acids, and

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therefore, the claimed probes and primers would hybridize only to human TANGO405 polynucleotide; 2) that the Examiner seems to be requiring that probes or primers hybridize under any conditions to only TANGO405, and this is not required for the claim nucleic acid fragment to be useful, that the Examiner has provided absolutely no evidence that he recited nucleic acid fragments would bind other "unknown proteins" (nucleic acids ?), and that nucleic acids of the lengths recited are clearly specific to human TANGO405. This argument is not persuasive for the following reasons: with respect to argument 1), it is a repeated argument as that presented in the last response, and had been addressed in the last Office Action.

With respect to argument 2), it is not Examiner's requirement that probes or primers hybridize under any conditions to only TANGO405, in order for the claim nucleic acid fragment to be useful. The issue is that the specification does not provide any other uses for the claimed fragment. Regarding the specific hybridization, as pointed out by applicants that the present TANGO405 shares high homology to other members of C-type lectin family, such as dectin-2, and the present specification does not disclose sequence regions specific for the nucleic acid encoding TANGO405, it is unclear how one may guarantee that a randomly selected nucleic acid fragment of 40 nucleotides from the molecule encoding the TANGO405 would specifically bind to the nucleic acid encoding the TANGO405.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 44 remains rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 44 is indefinite for the recitation of "*a* nucleic acid molecule of claim 1". "*The* nucleic acid molecule of claim 1" is suggested.

**Conclusion:**

No claim is allowed.

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**Advisory Information:**

Any inquiry concerning this communication should be directed to Dong Jiang whose telephone number is 571-272-0872. The examiner can normally be reached on Monday - Friday from 9:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



LORRAINE SPECTOR  
PRIMARY EXAMINER

Dong Jiang, Ph.D.  
Patent Examiner  
AU1646  
6/1/04